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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,717	01/28/2002	Douglas William Hamilton	7250-11	8819
7590	10/18/2004			EXAMINER KOSSON, ROSANNE
Thomas Q Henry Woodard Emhardt Naughton Moriarty & McNett Bank One Tower 111 Monument Circle Suite 3700 Indianapolis, IN 46204			ART UNIT 1651	PAPER NUMBER
			DATE MAILED: 10/18/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/889,717	HAMILTON ET AL.
	Examiner	Art Unit
	Rosanne Kosson	1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 10 September 2004.  
 2a) This action is **FINAL**.                            2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-28 is/are pending in the application.  
 4a) Of the above claim(s) 19-28 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-18 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claim 13 recites that cells locate partly within the channel and partly above the profile of the fiber. Are the cells located partly in the channel and partly out of the channel? The term "profile" of the fiber is not defined in the specification. Thus, the meaning of the claim is unclear, and a holding of indefiniteness is required.

Claim 16 recites the limitation "the fibres of different composition." There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-13, 15 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Curtis et al. (WO 95/22305). Curtis discloses a method of culturing eukaryotic cells

(epithelial cells and fibroblasts) on flexible substrates that are sheets with parallel longitudinal grooves and ridges. The sheets may be rolled to form round tubular fibers or folded to form longitudinally split fibers. The sheets may be stacked or formed into any other shape to form the shape needed for a specific anatomical site or surgical procedure. Thus, multiple layers or multiple fibers may be used. The channels as shown in the Abstract have a rectangular "U" cross-section. The sheets are up to 250  $\mu$  in thickness, with channel widths of preferably 1-10  $\mu$  and channel depths of preferably 0.3 to 5 times the width of a cell on a flat surface. The distance between the centers of two channels is generally 2-20  $\mu$ . The sheets or fibers may also have an array of protrusions in a square pattern to promote cell growth orientation. The cells grow in the valleys defined between adjacent rows of protrusions. The square pattern creates both longitudinal and transverse channels (see p. 7, 3<sup>d</sup> full paragraph, to p. 11, 1<sup>st</sup> paragraph). Cells growing along the fibers grow within and above the channels (see p. 19). Although the length and width of the sheets or fibers is not specifically indicated, to be used in a patient or in cell culture, they would inherently be between 5 mm and 500 mm in length. When a sheet less than 250  $\mu$  in thickness is rolled into a tube to form a fiber, the fiber may be less than 1000  $\mu$  in diameter. Thus, a holding of anticipation is required.

Claims 1-6, 8-13, 15 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Tokyo University (JP 04-322657, see also enclosed English translation). Tokyo University also discloses fibers with rectangular "U" shaped or "V" shaped

longitudinal channels for promoting oriented growth of cells, such as fibroblasts, epithelial cells, myoblasts and nerve cells. The channels are 0.1-1000  $\mu$  in width and in depth. More than one material may be used to make the fibers, and the material or materials may be formed into any shape required for its application (see paragraphs 12, 14, 17, 18). Cells growing along the fibers grow within and above the channels (see Fig. 1). As in the Curtis reference discussed above, although the length and width of the fibers is not specifically indicated, to be used in a patient or in cell culture, they would inherently be between 5 mm and 500 mm in length. With a channel width of 0.1-1000  $\mu$ , the fibers would have a diameter between 5 and 1000  $\mu$  (see Figs. 3 and 5). Thus, a holding of anticipation is required.

Claims 1-6, 8-11 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Hitachi Chemical Co. Ltd. (JP 04-262780, see also enclosed English translation). Hitachi Chemical also discloses fibers with rectangular "U" shaped and "V" shaped longitudinal channels for promoting oriented growth of cells, such as nerve cells. The channels are 0.1-1000  $\mu$  in width and in depth. The material used to make the fibers may be formed into any shape required for its application. The etching process used to make the channels, oxygen reactive ion etching or oxygen plasma treatment, produces alternating ridges that are relatively hydrophilic and channels that are relatively hydrophobic. Good orientation of cell growth is achieved because cell grow along and parallel to the ridges and not in the channels (see paragraphs 6, 7, 9 and Fig. 1). As in the Curtis reference discussed above, although the length and width of the

fibers is not specifically indicated, to be used in a patient or in cell culture, they would inherently be between 5 mm and 500 mm in length. With a channel width of 0.1-1000  $\mu$ , the fibers would have a diameter between 5 and 1000  $\mu$ . Thus, a holding of anticipation is required.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curtis et al. (WO 95/22305) in view of The University of Strathclyde (EP 419234, hereinafter referred to as "Strathclyde"). As discussed above, Curtis discloses a method of culturing eukaryotic cells (epithelial cells and fibroblasts) on flexible

substrates that are sheets with parallel longitudinal grooves and ridges. The sheets may be rolled to form round tubular fibers or folded to form longitudinally split fibers. The sheets may be stacked or formed into any other shape to form the shape needed for a specific anatomical site or surgical procedure. Thus, multiple layers or multiple fibers may be used. The channels as shown in the Abstract have a rectangular "U" cross-section. The sheets are up to 250  $\mu$  in thickness, with channel widths of preferably 1-10  $\mu$  and channel depths of preferably 0.3 to 5 times the width of a cell on a flat surface. The distance between the centers of two channels is generally 2-20  $\mu$ . The sheets or fibers may also have an array of protrusions in a square pattern to promote cell growth orientation. The cells grow in the valleys defined between adjacent rows of protrusions. The square pattern creates both longitudinal and transverse channels (see p. 7, 3<sup>d</sup> full paragraph, to p. 11, 1<sup>st</sup> paragraph). Cells growing along the fibers grow within and above the channels (see p. 19 ). Although the length and width of the sheets or fibers is not specifically indicated, to be used in a patient or in cell culture, they would inherently be between 5 mm and 500 mm in length. When a sheet less than 250  $\mu$  in thickness is rolled into a tube to form a fiber, the fiber may be less than 1000  $\mu$  in diameter. Curtis does not disclose a cell culture method in which the fibers are arranged in a scaffold or in which fibers of different compositions are layered or in which the parallel fibers are aligned on a permeable flat surface.

Strathclyde discloses a method of culturing cells in which fibers of two different materials are used. One type, for delivering a liquid nutrient medium (inflow) and removing metabolic waste products (outflow) is made of a hydrophilic semipermeable

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membrane, e.g., treated polysulfone, with a spongy outer layer. The other type, for delivering nutrient gases (O<sub>2</sub> and CO<sub>2</sub>) and removing waste gases, is made of a hydrophobic, microporous material, such as polypropylene. The two types of fibers may be arranged in alternating, parallel layers forming a scaffold. The scaffold is contained in bioreactor with permeable, flat sides that have inlet and outlet ports (see col. 1, line 43, to col. 6, line 19, in particular col. 3, lines 34-46; col. 3, line 58, to col. 4, line 18; and Figs. 10-16).

One of ordinary skill in the art at the time that the invention was made would have recognized that the cell culture method as disclosed in Curtis would have been modified by using layered fibers of two different types or fibers arranged in a scaffold because Strathclyde teaches that the arrangements using two different types of fibers in alternating layers allow for independent control of liquid medium and gases while minimizing the gradients produced by each. Strathclyde also teaches that layers in a scaffold can be arranged to deliver liquid medium and gases at a perpendicular angle, which allows shorter fibers to be used. Further, Strathclyde teaches that locating the fibers on a flat, permeable surface allows liquid medium and gases to be delivered to and removed from the cells on the fibers with inflow and outflow ports located close to the fibers. Thus, the artisan of ordinary skill would have been motivated to modify the cell culture method of Curtis with the additional features disclosed in Strathclyde for the advantages disclosed in Strathclyde. A holding of obviousness is therefore required.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson  
Examiner  
Art Unit 1651

rk  
2004-10-13



FRANCISCO PRATS  
PRIMARY EXAMINER